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| FORM PTO-1390 (REV. 01-2003) | | US DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE | ATTORNEY'S DOCKET NUMBER 124055 |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/536,459 | |
| INTERNATIONAL APPLICATION NO. PCT/JP2003/15005 | INTERNATIONAL FILING DATE November 25, 2003 | PRIORITY DATE CLAIMED November 25, 2002 | |
| TITLE OF INVENTION AGENT FOR TREATING RESPIRATORY DISEASES CONTAINING 4-HYDROXYPYPERIDINE DERIVATIVE AS ACTIVE INGREDIENT | | | |
| APPLICANTS FOR DO/EO/US Yasushige AKADA; Kazuyuki MATSUURA | | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | | |
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). c. <input type="checkbox"/> The International Application was filed in English. 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | | |
| Items 11 to 20 below concern document(s) or information included: | | | |
| <ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input type="checkbox"/> Other items or information: | | | |

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| U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5) 10/536,459 | INTERNATIONAL APPLICATION NO. PCT/JP2003/15005 | ATTORNEY'S DOCKET NUMBER 124055 | | | |
| 21. <input type="checkbox"/> The following fees are submitted: | | CALCULATIONS PTO USE ONLY | | | |
| BASIC NATIONAL FEE (37 CFR 1.492(a)): \$ 300.00 | | \$ | | | |
| SEARCH FEE (37 CFR 1.492(b)(1)-(3)): | | \$ | | | |
| International preliminary examination report or written opinion prepared by the USPTO as IPEA or ISA and favorable as to novelty, inventive step, and industrial applicability for all claims presented in the application entering the national stage \$ 0.00 | | | | | |
| International search fee (37 CFR 1.445(a)(2)) paid to USPTO as ISA \$ 100.00 | | | | | |
| International search report provided to USPTO no later than the time at which the search fee is paid \$ 400.00 | | | | | |
| All situations not provided for above \$ 500.00 | | | | | |
| EXAMINATION FEE (37 CFR 1.492(c)(1)-(2)): | | \$ | | | |
| International preliminary examination report or written opinion prepared by the USPTO as IPEA or ISA and favorable as to novelty, inventive step, and industrial applicability for all claims presented in the application entering the national stage \$ 0.00 | | | | | |
| All situations not provided for above \$ 200.00 | | | | | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)). | | \$ | | | |
| TOTAL PAGES OF APPLICATION OVER 100 (- 100) | ÷ 50 | = † | x 250 = | \$ | |
| round up to next integer | | | | | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | \$ | |
| TOTAL CLAIMS | - 20 | = | x 50.00 = | \$ | |
| INDEPENDENT CLAIMS | - 3 | = | x 200.00 = | \$ | |
| MULTIPLE DEPENDENT CLAIM(S)(if applicable) | | | + 360.00 = | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½. | | | | \$ | |
| SUBTOTAL = | | | | \$ | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). | | | | \$ | |
| TOTAL NATIONAL FEE = | | | | \$ | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | | | \$ | |
| TOTAL FEES ENCLOSED = | | | | \$ | |
| | | | | Amount to be refunded: \$ | |
| | | | | charged: \$ | |
| a. <input type="checkbox"/> Check No. _____ in the amount of \$ _____ to cover the above fees is enclosed. | | | | | |
| b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | |
| c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>15-0461</u> . A duplicate copy of this sheet is enclosed. | | | | | |
| d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. | | | | |  |
| SEND ALL CORRESPONDENCE TO: OLIFF & BERRIDGE, PLC Customer Number: 25944 | | | | | NAME: James A. Oliff REGISTRATION NUMBER: 27,075 |
| Date <u>September 14, 2005</u> | | | | | NAME: Jesse O. Collier REGISTRATION NUMBER: 53,839 |

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Yasushige AKADA et al.

Application No.: 10/536,459

Group Art Unit: 1623

Filed: May 25, 2005

Docket No.: 124055

For: AGENT FOR TREATING RESPIRATORY DISEASES CONTAINING 4-HYDROXYPYPERIDINE DERIVATIVE AS ACTIVE INGREDIENT

INFORMATION DISCLOSURE STATEMENT

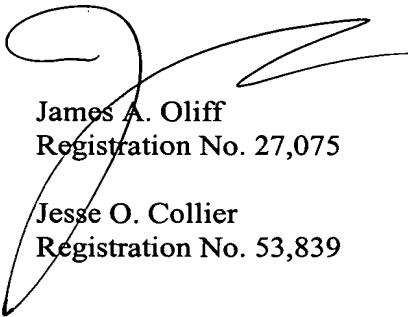
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date of this non-CPA application, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- 2. Relevance of the references is discussed in the present specification.

Respectfully submitted,



James A. Oliff
Registration No. 27,075

Jesse O. Collier
Registration No. 53,839

JAO:JOC/nxy

Date: September 14, 2005

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| <p>DEPOSIT ACCOUNT USE AUTHORIZATION</p> <p>Please grant any extension necessary for entry;</p> <p>Charge any fee due to our Deposit Account No. 15-0461</p> |
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| Form PTO-1449 (REV. 8-83) US Dept. of Commerce PATENT & TRADEMARK OFFICE | | | ATTY DOCKET NO. 124055 | | APPLICATION NO. 10/536,459 | | |
|---|----|---|--------------------------------------|---------|-------------------------------|-------|-----------|
| INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | | APPLICANTS Yasushige AKADA et al. | | | | |
| | | | FILING DATE May 25, 2005 | | GROUP 1623 | | |
| U.S. PATENT DOCUMENTS | | | | | | | |
| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | | CLASS | SUB CLASS |
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| FOREIGN PATENT DOCUMENTS | | | | | | | |
| | | DOCUMENT NUMBER | DATE | COUNTRY | | CLASS | SUB CLASS |
| | 1. | WO 93/02052 A1 | 02/04/1993 | WIPO | | | |
| | 2. | WO 00/06545 A1 | 02/10/2000 | WIPO | | | |
| | 3. | WO 02/22572 A2 | 03/21/2002 | WIPO | | | |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) | | | | | | | |
| | 4. | Bruno S. HUEGI et al.; "Synthesis and Pharmacological Studies of 4,4-Disubstituted Piperidines: A New Class of Compounds with Potent Analgesic Properties"; J. Med. Chem.; 1983; Vol 26; pp. 42-50. | | | | | |
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| EXAMINER | | | | | DATE CONSIDERED | | |
| Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | |